REMARKS

Claims 1 - 4, 8, 11 - 17, 19, 20, 23, and 28 have been rejected under 35 U.S.C. §103(a) as being unpatentable over Brekke. In response, each of the independent claims 1, 15, and 23 have been amended to expressly state that the present invention is an "open" system to supplement a patient's spontaneous respiration in treatment of respiratory failure, respiratory insufficiency, or sleep apnea syndrome, unlike Brekke. Brekke's invention is used to deliver anesthetic and/or oxygen for surgical procedures in the operating room, oral surgery office, or out-patient clinic that require access to the oral cavity, face, and neck. Brekke discloses three embodiments or configurations:

1. The first embodiment features an endotracheal tube 16 and is intended for use with a ventilator, such as in an operating room, as discussed at column 3, lines 25, *et seq.* The patient's trachea is blocked by an endotracheal tube cuff 20 and an inflatable barrier 18 seals the back of the oral cavity, as shown in figure 1 of the Brekke patent. Sponge rubber collars 34 and 36 also seal the patient's nostrils around the periphery of the nasal cannula 26 to obstruct spontaneous respiration through the nose. The patient is solely dependent on the fluctuating gas flow and volume supplied by the ventilator to simulate and support the respiratory cycle.

2. The second embodiment replaces the endotracheal tube with a nasalpharyngeal tube 44, which is used by an oral surgeon in an out-patient clinic or oral surgery office for administering anesthetic (environment II). It is only inserted after intravenous anesthetics have been administered to render the patient unconscious (column 5, line 20 - 21). Here again, an inflatable barrier 18a seals the back of the oral cavity to prevent aspiration of blood, saliva, and debris into the lungs. Sponge rubber collars 34, 36 block the nostrils. The patient is apparently intended to breathe in and out through the nasalpharyngeal tube 44 and nasal cannula 26. Anesthetics

and oxygen are delivered via the nasalpharyngeal tube. A one-way exhaust valve 38 on the cannula 26 allows the patient to exhale through the nasal cannula 26.

3. The third configuration uses the nasal cannula 26 by itself (without an endotracheal tube or nasalpharyngeal tube) to administer nitrous oxide or oxygen. This configuration is essentially little different than a conventional nasal cannula.

Brekke's first embodiment teaches away from the present invention by disclosing an endotracheal tube for use in a "closed" system in which spontaneous breathing is blocked by the endotracheal tube cuff 20 in the patient's trachea, the inflatable barrier 18 sealing the back of the patient's oral cavity, and the sponge rubber collars 34, 36 blocking the nostrils. Brekke discusses that his device can be used to administer anesthetic gases to a patient. A closed system is required for this purpose to prevent the escape of certain anesthetic gases into the surrounding room and to control the anesthetic dose to the patient. In addition, the patient must be sedated or unconscious to tolerate insertion of an endotracheal tube without stimulating the gag reflex. Likewise, as with all surgeries requiring an endotracheal tube, sedation must be continued during the operative procedure so the patient will continue to tolerate the endotracheal tube.

Brekke's second embodiment also teaches away from the present invention. It too is a closed system in which an inflatable barrier 18a seals the back of the patient's oral cavity, and sponge rubber collars 34, 36 block the nostrils. Here again, the patient must be rendered unconscious to tolerate insertion of the nasalpharyngeal tube 44 with an inflated cuff 18a without stimulating the gag reflex (column 5, lines 20 - 21). Anesthetic gas and sedation are continued through the procedure. The patient's reduced level of consciousness during the operation makes the patient prone to aspirating bone, blood and debris into the lungs. Though the barrier is designed to prevent aspiration, sedation must be continued to eliminate the gag reflex induced by the inflatable barrier.

In contrast to the closed systems disclosed by Brekke, the present invention is an "open" system in which a nasal catheter provides air/oxygen to supplement the patient's

spontaneous breathing without obstructing the patient's spontaneous breathing. In some cases, this can be enough to prevent having to put a patient with respiratory failure or insufficiency on ventilator life support with an endotracheal tube. Similarly, the high flow delivered through the nasopharyngeal catheter actually opens up the upper airway and prevents obstruction in patients with obstructive sleep apnea. The present invention can be used for extended periods of time or just periodically as needed by the patient. For example, the present invention can be used by a patient on a nightly basis to treat sleep apnea. The nasal catheter can be readily inserted and removed without patient sedation. It also allows the patient to continue talking, eating, and drinking in a normal manner, unlike Brekke.

As noted above, a primary purpose of an open system is to treat patients with respiratory failure or insufficiency, or sleep apnea syndrome, so that a ventilator will not become necessary. However, being placed on a closed system is often enough to push such a patient "over the edge." Patients with respiratory failure or insufficiency or sleep apnea have markedly increased work of breathing. It is not realistic to expect a patient with an impaired respiratory system to breathe in and out through a small-diameter tube without ventilator assistance in performing the work of breathing. The increased resistive loads caused by breathing in and out through a small-diameter tube can further fatigue the respiratory muscles. In addition, insertion and maintenance of an endotracheal tube or nasalpharyngeal tube into the trachea, as taught by Brekke, requires that the patient must be unconscious or sedated to avoid stimulating the patient's gag reflex. Sedation or anesthesia markedly impairs the neurologic respiratory drive and is contra-indicated for patients with respiratory failure or insufficiency, or sleep apnea syndrome who must rely on their spontaneous respirations.

All of the independent claims in the present application also require that the distal end of the nasal catheter supplies air/oxygen into the patient's distal nasopharynx or oropharynx (claim 1, lines 10 - 11; claim 15, lines 11 - 12; and claim 23, line 7). In contrast, the distal end of the endotracheal tube disclosed by Brekke extends past the patient's nasopharynx, oropharynx, and larynx, and into the patient's trachea.

Furthermore, all of the independent claims require a continuous gas flow rate of approximately 4 to 40 liters per minute. Flow is one-way through the catheter and the patient does not exhale back through the device. This high flow rate of gas is delivered into the patient's distal nasopharynx or oropharynx, at a point relatively high in the patient's respiratory tree. A portion of this gas flows into the patient's trachea and lungs to deliver oxygen, flush carbon dioxide from the patient's lungs, reduce physiologic dead space and reduce the work of breathing. If the gas delivered by the catheter has an elevated oxygen content, it will tend to enrich the oxygen content of all of the gas in the patient's respiratory tree, and thus makes the patient's spontaneous breathing more effective. However, a large portion of the gas exiting the catheter is exhaled or flows unrestricted out of the patient's airway and is lost. Continuous flow rates of 4 to 40 liters per minute are physiologically possible with open systems because excess gas can readily escape from within the patient. However, this is not possible with a closed system such as Brekke in which the airway is blocked by the endotracheal tube cuff 20 in the patient's trachea and the inflatable barrier 18 sealing the back of the patient's oral cavity. In such a closed system, the ventilator must precisely follow a sinusoidal curve for the delivery of flow and volume that simulates a breath. Preset maximum and minimum values are dictated by the patient's respiratory capacity. In patients with impaired lung and respiratory muscle capacity, a continuous flow that is also delivered on exhalation through a small-diameter nasalpharyngeal tube in a closed system will build up backpressure and an increased resistance to exhalation through the tube. This pressure can cause further injury to the lungs and fatigue of already compromised respiratory muscles through increased work load.

Regarding claims 2 - 3, 15 - 22 and 24, nothing in Brekke teaches or suggest a catheter that can be trimmed to a desired length. The endotracheal tube disclosed by Brekke has a fixed length. The cuff at the distal end of the endotracheal tube and the conduits at the upper end of the Brekke device would make it very difficult to trim such a device while maintaining its intended functionality. Column 4, lines 46 *et seq.* of the Brekke patent discusses adjusting the position of the nasalpharyngeal tube in Brekke's

second embodiment, but not trimming its length. With regard to claims 24 and 25, nothing in Brekke teaches or suggests cutting the catheter so its distal tip will have a desired position relative to the patient's uvula.

Claims 5, 6, and 18 have been rejected under 35 U.S.C. §103(a) as being unpatentable over Brekke in view of Dali et al. Claims 7 and 19 have been rejected under 35 U.S.C. §103(a) as being unpatentable over Brekke in view of Spofford et al. Claims 9, 10, 21, 22, 26, and 27 have been rejected under 35 U.S.C. §103(a) as being unpatentable over Brekke in view of Daniell et al. In response, Applicant notes that these are dependent claims and restates the previous comments concerning amended independent claims 1, 15, and 23.

Favorable reconsideration is respectfully requested.

Respectfully submitted,

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Marked Up Version of Amended Claim 1:

1. **(thrice amended)** A nasopharyngeal catheter **[to deliver]** **for open delivery of** a **continuous** flow of air/oxygen into a patient's distal nasopharynx or oropharynx to supplement a patient's spontaneous respiration **in treatment of respiratory failure, respiratory insufficiency, or sleep apnea syndrome**, said nasopharyngeal catheter comprising:

a nasal catheter having a proximal end and a distal end adapted to extend through a patient's nose and into the patient's distal nasopharynx or oropharynx without obstructing the patient's spontaneous respiration;

a delivery tube adapted to extend below the patient's nostril connected to the proximal end of the nasal catheter; and

a gas source delivering a **continuous** flow of air/oxygen at a rate of approximately 4 to 40 liters per minute through the delivery tube and nasal catheter into the patient's distal nasopharynx or oropharynx.

Marked-Up Version of Amended Claim 15:

15. **(thrice amended)** A nasopharyngeal catheter **[to deliver]** **for open delivery of** a **continuous** flow of air/oxygen into a patient's distal nasopharynx or oropharynx to supplement a patient's spontaneous respiration **in treatment of respiratory failure, respiratory insufficiency, or sleep apnea syndrome**, said nasopharyngeal catheter comprising:

a nasal catheter having a proximal end and a distal end adapted to extend through a patient's nose and into the patient's distal nasopharynx or oropharynx without obstructing the patient's spontaneous respiration, said catheter being made of a flexible material that can be trimmed to a desired length;

a delivery tube adapted to extend below the patient's nostril having a connector for removable attachment to the proximal end of the nasal catheter; and

a gas source delivering a **continuous** flow rate of approximately 4 to 40 liters per minute through the delivery tube and nasal catheter into the patient's distal nasopharynx or oropharynx.

Marked-Up Version of Amended Claim 23:

23. **(twice amended) [A]** **An open delivery** method for providing a supplemental **continuous** flow of air/oxygen to a spontaneously breathing patient **in treatment of respiratory failure, respiratory insufficiency, or sleep apnea syndrome**, the method comprising:

advancing a nasopharyngeal catheter through a patient's nostril until the distal tip of the catheter is located in the patient's distal nasopharynx or oropharynx without obstructing the patient's spontaneous respiration; and

supplying air/oxygen through the catheter at a **continuous** flow rate of approximately 4 to 40 liters per minute into the patient's distal nasopharynx or oropharynx.